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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/063,559	05/02/2002	David C. Kulp	3291.7	9768

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EXAMINER	
SMITH, CAROLYN L	
ART UNIT	**PAPER NUMBER**
1631	

DATE MAILED: 06/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/063,559	KULP ET AL.	
	Examiner	Art Unit	
	Carolyn L. Smith	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 March 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *19,49-51,64,65 and 67-72* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *19,49-51,64,65 and 67-72* is/are rejected.

7)☒ Claim(s) *67* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicant's amendments and remarks, filed 3/31/06, are acknowledged. Amended claims 19, 49, 67-69, and 72 are acknowledged.

Applicant's arguments, filed 3/31/06, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from the previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claims 19, 49-51, 64-65 and 67-72 are herein under examination.

Claim Objection

Claim 67 is objected to because of the following informality: The term "include" is referring to the term "correlation" and should therefore be in singular form as opposed to plural form. Appropriate correction is required.

Claim Rejections - 35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 19, 49-51, 64-65, and 67-72 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

This rejection is necessitated by amendment.

Claims 19, 49, and 72 recite the limitation "the names" which lacks clear antecedent basis. While the claim previously recites "one or more names", the limitation "the names" does not take into account the scenario of only one name. It is unclear if the singular scenario is excluded on purpose or if Applicant intends "the names" to include the full limitation of "one or more names". Clarification of this issue via clearer claim wording is requested. Claims 50-51, 64-65, and 67-71 are also rejected due to their dependency from claims 19 and 49.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 19, 49-51, 64-65, and 67-72 are rejected under 35 U.S.C. 103(a) as being unpatentable over Maslyn et al. (US 6,408,308) in view of Chin et al. (US 6,470,277).

This rejection is maintained.

Maslyn et al. describe a system and method for generating, analyzing, and storing datasets from probe sequences (title). Maslyn et al. describe a manufacturer microarray with identification of the sites having probes corresponding to a particular transcript (col. 4, lines 49-52). Maslyn et al. describe correlating a particular gene (biological sequence) or elements on the microarray with the probe design using microarray layout data and design data files for summarization of data (col. 6, lines 22-28). Figure 9 describes a user defined query (530) where

selected datasets are retrieved and provided based on user defined selection (531) followed by comparison (correlation) to other datasets (532/534/536/544/546) including filters to select specified elements of the dataset such as protein function (542 and col. 12, lines 11-17), ending in a viewing of the data (538). Maslyn et al. describe using gene targets and array elements that are complementary sequences to mRNA molecules (col. 1, lines 24-45) and probe arrays containing a plurality of probe sets with one or more probes representing a number of genes (title and col. 4, lines 40-56), as stated in the preamble of instant claims 19, 49, and 72. Maslyn et al. describe retrieving a query over a network (Figure 1; col. 3, lines 23-57) a microarray manufacturer providing data on the specific transcripts represented on the microarray and identifying the site or sites having probes corresponding to a particular transcript (col. 4, lines 49-52) including Image identifier (Image ID) as well as Sequence ID (col. 9, lines 49-55 and col. 10, lines 15-16) with displaying names of datasets resulting from a user defined query (col. 11, lines 29-41) which represents receiving a query over a network involving arbitrarily manufacture-defined probe-set identifiers with names, as stated in instant claims 19 and 49. Maslyn et al. describe a client computer with web browser (42) and keyboard (154) (Figure 4B and col. 11, lines 24-41) with the user selects the particular names of datasets to be compared by selecting or highlighting one or more dataset names to include in a hybridization working set (col. 11, lines 38-46) wherein the pseudoarray data set describes a hybridization image including all or a subset of the abundance data for a hyb-image (col. 11, lines 47-53) which represents a user selecting the names into a web browser operated on a user-side client and the names come to the attention of the user from results of one or more experiments performed using the biological probe arrays, as stated in instant claims 19, 49, and 72. Maslyn et al. describe a

processing system with procedures and tables that store information identifying element data from microarrays (abstract), identifying genes via gene expression data analysis (col. 1, lines 24-27), and identifying the site or sites having probes corresponding to a particular transcript (col. 4, lines 49-52) including Image identifier (Image ID) and Sequence ID (col. 9, lines 49-55 and col. 10, lines 15-16) with displaying names of datasets resulting from a user defined query (col. 11, lines 29-41) which represents identifying the gene that corresponds with each name using data that associates name, identified probe set, and corresponding gene, as stated in instant claims 19, 49, and 72. Maslyn et al. describe filtering functions according to abundance, protein function (comparisons) as well as Figure 10A with a "build query" region with a BLAST search (sequence search) (col. 12, lines 1-5) and query parameters involving a hierarchy of enzymes including oxidoreductases and transferases (protein families) where the user can select any combination of query data across categories (col. 12, lines 32-38). Maslyn et al. describe a tables with array elements, transcript ID, protein family information, and BLAST searches (i.e. Figures 7C and 10A) as well as a relational operation JOIN that allows a program to retrieve data from two or more tables based on matching field values (col. 7, second paragraph) and display of generated lists (col. 12, lines 39-44) which represents correlating each gene or EST with a set of protein family data using a protein sequence that corresponds to the gene or EST to identify the protein family, as stated in instant claims 19, 49, and 72. Maslyn et al. describe displaying generated lists (col. 12, lines 39-44) and other results to the client computer over the network to the user via a web browser (col. 3, line 23 to col. 4, line 35), as stated in instant claims 19, 49, and 72. Maslyn et al. describe microarray design information including data that specifies global characteristics of each microarray, array element data including sequence information, including

protein sequences (col. 2, lines 19-25 and 34-39), as stated in instant claims 19 and 49. Maslyn et al. describe correlating the elements on the microarray with the probe design (col. 6, lines 22-25). Maslyn et al. describe microarrays generating raw image or expression data and each image data of hybridization experiments is associated with a unique Image Identifier (col. 7, line 58 to col. 8, line 3) which represents identifiers identifying probe sets from the results of one or more experiments performed using biological probe arrays, as stated in instant claims 19, 49, and 72. Maslyn et al. describe generating data from a microarray composed of nucleic acid probe sequences representing genes or gene fragments (biological sequences) (col. 4, lines 40-43) such that each microarray represents a probe-set as well as a correlation between probe-set identifiers and genes. Maslyn et al. describe selecting any combination of query criteria by selecting data across various categories, such as transcript, microarray (a probe-set), sample, and data source (col. 12, lines 33-38). Figure 10A describes protein families and query parameters such as a BLAST search (593) (i.e. gene sequence comparison), molecular function and structural proteins (594) (protein information) (col. 11, lines 29-46 and col. 12, lines 1-2) as well as a relational operation JOIN that allows a program to retrieve data from two or more tables based on matching field values (col. 7, second paragraph) which represents identification of a biological molecule as well as correlating sequence with protein family data via sequence similarity, as stated in instant claim 68. Maslyn et al. describe tables that store information identifying a microarray technology type and microarray design information (abstract). Maslyn et al. describe microarray design information includes location and sequence information (first data set) of the array elements (col. 2, lines 20-25). Maslyn et al. describe providing probes for up to about 10,000 genes (col. 4, lines 52-56). Maslyn et al. describe organizing raw expression data with

other user-defined data into a format suitable for loading into the expression database (col. 6, lines 9-12). Maslyn et al. describe displaying and comparing data that is stored in external datasets (col. 12, lines 26-31). Figure 1 describes the use of a sequence database. Merriam-Webster online dictionary defines domain as "a region distinctively marked by some physical feature", such that a structural proteins (Figure 10A) represent protein domain information, as stated in instant claims 51 and 65. Maslyn et al. describe a protein function menu to allow users to select elements (probes) by their associated protein function (col. 1, lines 32-34 and col. 14, lines 34-36) which represents a correlation ("establish a mutual or reciprocal relation between", definition of correlate according to the Merriam-Webster online dictionary) between the microarray gene element data with the protein data. Figure 10B demonstrates datasets the user will define (602) and datasets the user will view (608). Maslyn et al. describe generating data from a microarray composed of nucleic acid probe sequences representing genes or gene fragments (biological sequences) (col. 4, lines 40-43) such that each microarray represents a probe-set. Maslyn et al. describe an information processing system storing expression data for polypeptide sequences (col. 2, lines 36-39). Maslyn et al. describe correlating a particular gene (biological sequence) or elements on the microarray with the probe design using microarray layout data and design data files for summarization of data (col. 6, lines 22-28). Maslyn et al. describe a network server, UNIX operating system, application software module, and a relational database management system (RDBMS) wherein data pass to JAVA classes such that results are displayed to the client computer (user) (col. 3, lines 39-41 and col. 4, lines 22-26; Figure 1) which represent an output manager to provide data to user as well as an input manager, determiner, and correlator, as stated in instant claim 49. Figure 2 shows information flowing

from a database to a query to results to a users computer. Maslyn et al. do not describe "typing" name selection into a web browser, aligning a consensus sequence, implementing a plurality of Hidden Markov Models, and correlation determination by a Hidden Markov Model value above a threshold.

Chin et al. describe using user interface input devices, such as a keyboard to input information into a computer system or network (col. 5, first and second paragraphs) as well as client systems enabling users to access and query information stored by the server system via a web browser, including probe information (col. 4, lines 56-61 and Figures 1, 2, 8) via inputting DNA sequences (col. 6, line 25; co. 7, lines 25-34) which represents typing the name selection into a web browser. Chin et al. describe performing polypeptide sequence comparisons with HMM (Hidden Markov Model) algorithms (col. 9, lines 15-17 and col. 10, lines 51-55) which is outputted to a stored database (col. 9, lines 66-67). Chin et al. describe performing HMM with the predicted protein for protein comparisons, aligning, determining the percent identity with the target and query sequence and a consensus sequence (col. 10, line 51 to col. 11, line 5), as stated in instant claims 67-71. Chin et al. describe correlating various types of information and storing it in a format easily assessed by researchers (col. 2, lines 6-9). Chin et al. describe two or more sequences exhibit substantial sequence similarity if sequences have at least 70% amino acid residue or nucleic acid identity when compared and aligned for maximal correspondence as measured using a particular sequence comparison algorithm with probability values which are grouped as similar after examination of alignments (col. 6, line 65 to col. 7, line 25) which represents correlation determination above a threshold value, as stated in instant claim 70.

Maslyn et al. state that microarray-based experiments are generating increasing volumes of expression information that needs to be generated, stored, and provided in an effective manner (col. 2, lines 1-3). Chin et al. also state the need for techniques able to correlate various types of information and store it in a format easily assessed or queried by researchers (col. 2, lines 4-9). It would have been obvious to the person of ordinary skill in the art at the time the invention was made to analyze protein expression microarray data (col. 2, lines 27-39) as stated by Maslyn et al. and store it with microarray design information including sequence information (col. 2, lines 20-25), such as alignments via HMM, as stated by Chin et al. (col. 6, line 65 to col. 7, line 4 and col. 7, lines 47) and via BLAST, as stated by Maslyn et al. (col. 12, lines 1-2). The person of ordinary skill in the art would have been motivated to make these modifications of various homology search algorithms with DNA and protein sequence databases (Chin et al., col. 6, lines 35-49) in order to find related sequences and further correlate information (Chin et al., col. 6, lines 35-37) that may prevent, ameliorate, or affect a variety of diseases or physiological states (Chin et al., col. 1, lines 34-36). It would have been further obvious to a person of ordinary skill in the art at the time the invention was made to modify the method of Maslyn et al. by typing in name selections as stated by Chin et al. wherein the motivation would have been to use all types of input devices and ways to input information into a computer system and network in order to extract and integrate information and results from various analyses to identify genes that which may prevent, ameliorate, or affect a variety of diseases or physiological states, as stated by Chin et al. (col. 1, lines 34-36; col. 2, third paragraph; and col. 5, second paragraph)

Therefore, Maslyn et al. in view of Chin et al. motivate the limitations of the instant invention.

Applicants argue that Maslyn et al. requires the user to make selections from graphical representations while the claimed invention is not restricted to this type of user selection. This statement is found unpersuasive as the instant claims recite open claim language and thus do not exclude the selection technique recited by Maslyn et al., therefore the examiner maintains that Maslyn et al. teaches user selection. Applicants argue that Table 1 does not include a name that specifies the identity of a probe set. This statement is found unpersuasive as Table 1 recites a HybID and Image ID (i.e. ID of an entire probe set) and SummaryElementID (unique identifier for each element [i.e. probe] on a microarray). It is noted that a probe set may comprise a single probe, as stated in the instant claims. Maslyn et al. disclose displayed dataset names including a hybridization working set (col. 11, lines 36-46 and Figure 10B) which also identifies a probe set. Applicants argue that the "arbitrarily assigned" name is based on the manufacturers' preference or convenience as opposed to assigning a name based on an intrinsic or factual feature associated with the probe set. It is noted that the same dictionary also defines "arbitrary" as "depending on individual discretion (as of a judge) and not fixed by law". It is further noted that Maslyn et al. disclose a microarray manufacturer providing data on the specific transcripts represented on the microarray and identifying the site or sites having probes corresponding to a particular transcript (col. 4, lines 49-52) including Image identifier (Image ID) as well as Sequence ID (col. 9, lines 49-55 and col. 10, lines 15-16) which represent arbitrarily manufacture-defined probe-set identifiers with names, or names based on the manufacturers' preference. Sequence IDs represent randomly selected names, because there are many ways to ID a sequence, and the

manufacturer picks one to suit his/her preference. Applicants argue that the Image ID is not an identifier of a probe set because the ImageID does not specifically identify a probe set that is one of a plurality of probe sets on an array. This statement is found unpersuasive as a plurality of probe sets may include the entire set of probes as well as individual probes as individual probe sets. Applicants argue that Sequence ID is not an identifier of a probe set. This statement is found unpersuasive as a probe set may comprise a single probe, as stated in the instant claims and a characteristic of the array element (i.e. probe) (col. 1, fourth paragraph) is one way of identifying a probe and its probe set. Applicants argue that sequence identifiers typically employed are assigned for sequence information such as GenBank accession numbers. This argument about GenBank is moot as is does not seem to have any relevance to the CLAIMED limitations. Applicants argue that the phrase "names of datasets", as cited by Maslyn et al. (col. 9), does not identify a specific probe or probe set. This statement is found unpersuasive as Maslyn et al. disclose dataset names to include a hybridization working set (col. 11, lines 34-53) which represents identification of a probe set. Applicants argue that the amended claims clarify how the user selects (i.e. by typing) that distinguishes the claims from the described selection of Maslyn et al. This statement is found unpersuasive as a user typing the selection of a name is obvious as described above with Maslyn et al. in view of Chin et al. Maslyn describe a client computer with web browser (42) and keyboard (154) (Figure 4B and col. 11, lines 24-41) wherein the user selects the particular names of datasets to be compared by selecting or highlighting one or more dataset names to include in a hybridization working set (col. 11, lines 38-46). Chin et al. describe using user interface input devices, such as a keyboard to input information into a computer system or network (col. 5, first and second paragraphs) and client

systems enabling users to access and query information stored by the server system via a web browser (col. 4, lines 56-61), including probe information (Figures 1, 2, 8) and input DNA sequences (col. 6, line 25; co. 7, lines 25-34) which represents typing the name selection into a web browser.

Applicants again argue that the cited references do not describe receiving a user selection of one or more names each arbitrarily assigned by a probe array manufacturer to specifically identify a probe set, where the user types the selection of the names into a web browser. This statement is found unpersuasive as Maslyn et al. disclose retrieving a query over a network (Figure 1; col. 3, lines 23-57) a microarray manufacturer providing data on the specific transcripts represented on the microarray and identifying the site or sites having probes corresponding to a particular transcript (col. 4, lines 49-52) including Image identifier (Image ID) as well as Sequence ID (col. 9, lines 49-55 and col. 10, lines 15-16) with displaying names of datasets resulting from a user defined query (col. 11, lines 29-41) which represents receiving a query over a network involving arbitrarily manufacture-defined probe-set identifiers with names. Maslyn et al. describe a client computer with web browser (42) and keyboard (154) (Figure 4B and col. 11, lines 24-41) with the user selects the particular names of datasets to be compared by selecting or highlighting one or more dataset names to include in a hybridization working set (col. 11, lines 38-46). In addition, Chin et al. describe using user interface input devices, such as a keyboard to input information into a computer system or network (col. 5, first and second paragraphs) as well as client systems enabling users to access and query information stored by the server system via a web browser (col. 4, lines 56-61), including probe information (Figures 1,

2, 8) via inputting DNA sequences (col. 6, line 25; co. 7, lines 25-34) which represents typing the name selection into a web browser which represents typing as recited in the instant claims. Applicants argue that neither prior art reference disclose identifying a gene or EST that corresponds with each selected arbitrary name, specifically identified probe set, and the corresponding gene or EST. This statement is found unpersuasive as Maslyn et al. disclose a processing system with procedures and tables that store information identifying element data from microarrays (abstract), identifying genes via gene expression data analysis (col. 1, lines 24-27), and identifying the site or sites having probes corresponding to a particular transcript (col. 4, lines 49-52) including Image identifier (Image ID) and Sequence ID (col. 9, lines 49-55 and col. 10, lines 15-16) with displaying names of datasets resulting from a user defined query (col. 11, lines 29-41). Applicants' arguments are deemed unpersuasive for the reasons set forth above, therefore the rejection is maintianed.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR §1.6(d)). The Central Fax Center number for official correspondence is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carolyn Smith, whose telephone number is (571) 272-0721. The examiner can normally be reached Monday through Thursday from 8 A.M. to 6:30 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang, can be reached on (571) 272-0811.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instruments Examiner Tiffany Tabb whose telephone number is (571) 272-0556.

June 5, 2006

MARJORIE A. MORAN
PRIMARY EXAMINER

Marjorie A. Moran
6/12/06